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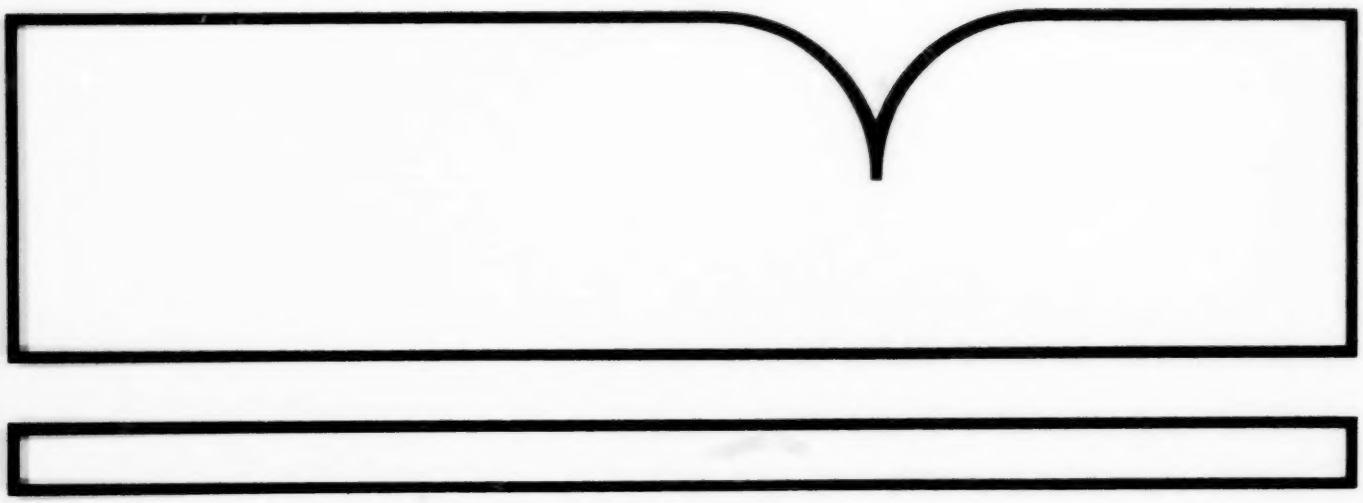
Pesticede Fact Sheet
Number 119: Fenbutatin-oxide

(U.S.) Environmental Protection Agency
Washington, DC

31 Mar 87



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PERFORMER: Environmental Protection Agency, Washington, DC. Office of Pesticide Programs.
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The document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale on a specific pesticide or group of pesticides. Description of Chemical: Generic name - bis(tris(2-methyl-2-phenylpropyl)tin) oxide or hexakis(2-methyl-2-phenylpropyl)-distannoxane; Common name - Fenbutatin-oxide; Trade name - Vendex, Fenbutatin oxyde, SD 14114, Torque, Neostanox, and Osadan; Pesticide type - Arcaricide; Use Patterns and Formulations: Application sites - fruit crops, field crops, and ornamentals.

KEYWORDS: *Pesticides, *Acaricides, *Toxic substances, *Fenbutatin oxide.

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United States
Environmental Protection
Agency

Office of Pesticides and Toxic Substances
Office of Pesticide Programs (TS-766C)
Washington, DC 20460

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EPA

Pesticide Fact Sheet

Name of Chemical: Fenbutatin-oxide

Reason for Issuance: Issuance of Registration Standard

Date Issued: MAR 31 1987

Fact Sheet Number: 119

1. Description of Chemical

-Generic Name: bis[tris(2-methyl-2-phenylpropyl)tin] oxide or hexakis(2-methyl-2-phenylpropyl)-distannoxane

-Common Name: Fenbutatin-oxide

-Trade Name: Vendex, Fenbutatin oxyde, SD 14114, Torque, Neostanox, and Osadan

-EPA Shaughnessy Number: 104601

-Chemical Abstracts Service (CAS) Number: Fenbutatin-oxide 13356-08-6

-Year of Initial Registration : 1974

-Pesticide Type: Acaricide

-Chemical Family: Organotin

-U.S. Producer: E.I. duPont de Nemours and Company

2. Use Patterns and Formulations

-Application sites: fruit, field crops, and ornamentals

-Types and method of applications: Foliar application by ground equipment only

-Application rates: 0.5 to 2.0 lb a.i. per acre

-Types of formulations: technical, wettable powder and flowable concentrate

-Usual carriers: Confidential Business Information

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3. Science Findings

Chemical Characteristics:

Technical fenbutatin-oxide is a white crystalline solid with a melting point at around 145°C, that is insoluble in water and slightly soluble in aromatic solvents. The empirical formula is $C_{60}H_{78}OSn_2$ and the molecular weight is 1053.

Toxicological Characteristics:

-Acute Oral: Data Gap
-Acute Dermal: >2000 mg/kg (rabbit)
-Primary Eye Irritation: Severe eye irritant (rabbit), Toxicity Category I
-Acute Inhalation: Data Gap
-Primary Skin Irritation: Mild skin irritant (rabbit)
-Dermal Sensitization: Not a dermal sensitizer (guinea pig)
-Major routes of exposure: Dermal followed by inhalation- Human exposure occurs from mixing, loading and application Exposure can be reduced by the use of goggles or face shield and protective clothing.
-Oncogenicity: A rat chronic/oncogenicity study showed no oncogenic effects at the highest dose tested (600 ppm). Mouse oncogenicity study: Data Gap
-Metabolism: Data Gap
-Teratology: Not teratogenic in rats (No Effect Level of 60 mg/kg with highest dose tested) or rabbits (No Effect Level of 5 mg/kg).
-Reproduction: Data Gap
-Mutagenicity: Data Gap

Physiological and Biochemical Characteristics

-Mechanism of Pesticide Action: It is suspected that fenbutatin-oxide inhibits adenosine triphosphate (ATP) enzymes. That is, it paralyzes the insects cardiovascular and respiratory systems by inhibiting oxidative phosphorylation.
-Metabolism and perisistence in plants and animals: Available data demonstrate that fenbutatin-oxide is relatively persistent on leaf surfaces and fruit and is gradually degraded to dihydroxy-bis-(2-methyl-2-phenylpropyl) stannane, 2-methyl-2-phenylpropyl stannonic acid and inorganic tin. Although submitted metabolism studies are not adequate to assess the nature of fenbutatin-oxide in animals, metabolites of fenbutatin-oxide were identified in feces of dairy cattle.

Environmental Characteristics

-Available data are insufficient to fully assess the environmental fate of fenbutatin-oxide. Data gaps exist for all required studies. The data required in this Standard will also allow us to assess the potential of this pesticide to contaminate groundwater.

Ecological Characteristics

-Acute avian oral toxicity: LD_{50}> 2510 mg/kg for Bobwhite Quail (nontoxic).
-Avian dietary toxicity: LC_{50}> 5620ppm for Mallard Duck (nontoxic). Supplemental data indicate an LC_{50} of 5065 ppm for Bobwhite Quail (nontoxic).
-Freshwater fish acute toxicity: LC_{50} = 0.0017 ppm for Rainbow trout (very highly toxic). LC_{50} = 0.0048 ppm for Bluegill sunfish (very highly toxic).
Freshwater aquatic invertebrate toxicity: Supplemental data indicate that an LD_{50} value for freshwater invertebrates is 0.040 ppm (very highly toxic).

Tolerance Assessment

-Tolerances have been established for residues of fenbutatin-oxide in a variety of raw agricultural commodities including meat, fat and meat by products (refer to 40 CFR 180.362 for listing of tolerances), and in processed food (21 CRF 193.236) and feed (21 CFR 561.255).
-The Agency is unable to complete a full tolerance assessment for the established tolerances due to residue chemistry and toxicology data gaps.

	Tolerances (ppm)			(MRL)
Commodity	U.S.	Canadian	Mexican	Codex
Almonds	0.5	-	-	-
Almonds, hulls	80.0	-	-	-
Apples	15.0	3.0	-	5.0
Cattle,fat	0.5	-	-	-
Cattle,meat by product	0.5	-	-	-
Cattle,meat	0.5	-	-	0.02
Cherries,sour	6.0	-	-	5.0
Cherries,sweet	6.0	-	-	5.0
Citrus fruits	2.0	2.0	-	5.0
Cucumber	4.0	0.5	-	1.0
Eggplant	6.0	-	-	1.0
Eggs	0.1	-	-	-
Goats,fat	0.5	-	-	-
Goats,meat by product	0.5	-	-	-
Goats,meat	0.5	-	-	-
Grapes	5.0	-	-	5.0
Hogs,fat	0.5	-	-	-
Hogs,meat by products	0.5	-	-	-
Hogs,meat	0.5	-	-	-
Horses,fat	0.5	-	-	-
Horses,meat by product	0.5	-	-	-
Horses,meat	0.5	-	-	-
milk fat	0.1	-	-	-

Commodity	Tolerances (ppm) U.S.	Canadian	Mexican	(MRL) Codex
Papayas	2.0	-	-	-
Pecans	0.5	-	-	-
Peaches	10.0	-	-	7.0
Pears	15.0			
Plums	4.0	-	-	3.0
Poultry,fat	0.1	-	-	-
Poultry, meat by products	0.1	-	-	-
Poultry,meat	0.1	-	-	-
Prunes	4.0	-	-	-
Sheep,fat	0.5	-	-	-
Sheep, meat by products	0.5	-	-	-
Sheep,meat	0.5	-	-	-
Strawberries	10.0	-	-	-
Walnuts	0.5	-	-	-
Apple pomace,dried	20.0	-	-	-
Citrus pulp,dried	7.0	-	-	-
Grape pomace,dried	100	-	-	-
Raisin waste	20.0	-	-	-
Prunes,dried	8.0	-	-	-
Raisins	20.0	-	-	-

-The data for the combined residues of fenbutatin-oxide and its organotin metabolites in or on almonds, almond hulls, apples, cherries(sweet and sour), citrus fruits, eggplant, grapes, papayas, peaches, pears, pecans, plums, raspberries, strawberries and walnuts are adequate to support the established tolerances.

-Data are not adequate to support the established tolerance for residues in or on cucumbers. Processing studies are required for apples, citrus fruits, grapes and plums.

-An acceptable Daily Intake (ADI) of 0.05 mg/kg/day, based a 2 year rat study has been established using a 100 fold safety factor. The Maximum Permissible Intake (MPI) is 3.0 mg/kg/day for a 60 kg person. The Theoretical Maximum Residue Contribution (TMRC) to the human diet from the existing tolerances is 0.0357 mg/kg/day for a 1.5 kg diet which is 71.4% of the MPI.

4. Summary of Regulatory Position

A. The Agency is requiring the submission of acute aquatic toxicity data and aquatic field monitoring data on the end-use formulations and aquatic life stage data and avian reproduction data on the technical formulation in order to complete the wildlife risk assessment.

B. Because of California incidence reports and the fact that this chemical is acutely toxic due to adverse eye effects, the Agency is requiring a 24 hour reentry interval, as established by California and Texas, until the Agency has received and evaluated the required reentry data.

C. Because of acute toxicity (eye effects), the Agency is requiring that all fenbutatin-oxide product labels contain protective clothing statements for early reentry.

D. No new tolerances or new food uses will be granted until the Agency has received data to evaluate dietary exposure to fenbutatin-oxide.

E. Based on fenbutatin-oxide use pattern and toxicity data, the Agency, in cooperation with the Fish and Wildlife Service, has determined that fenbutatin-oxide does not trigger endangered species concerns at this time. No endangered species labeling is required. If the required monitoring data indicate a hazard, then a re-evalution will be conducted.

F. The Agency has determined that the following data are essential to the Agency's assessment and should receive a priority review as soon as they are received by the Agency:

158.140 Reentry Protection

132-1 Foliar Dissipation (Re-entry)

158.145 Ecological Effects

72-4 Fish Early Life Stage and Aquatic Invertebrate Life Cycle
72-3 Acute Toxicity- Aquatic Estuarine and Marine Organism
72-7 Field Testing for Aquatic Organism

G. The Agency is requiring that the fenbutatin-oxide organotin metabolites be listed separately in the tolerance regulation so that established tolerances can be made compatible with the Maximum Residue Limits established by the Codex Alimentarius Commission.

5. Summary of Major Data Gaps

-The following studies are required to assess the toxicological characteristics of technical fenbutatin-oxide:
Acute Oral, Acute Inhalation, 90 Day Feeding (non-rodent), 21 Day Dermal Toxicity, Chronic Toxicity (non-rodent), Oncogenicity (mouse), 2 Generation Reproduction, Mutagenicity and General Metabolism Testing.

-The following data are required to fully characterize fenbutatin-oxide's environmental fate: Re-entry (foliar dissipation), Hydrolysis, Photodegradation (in water and on soil), Aerobic and Anaerobic Soil Metabolism, Leaching, Volatility (Lab), Soil Dissipation, Rotational Crops (Confined), and Accumulation in fish.
-Additional residue studies on commodities, animal metabolism studies, and storage stability studies are required to support existing tolerances.
-The following data are required to complete a wildlife risk assessment: Avian Subacute Dietary Toxicity, Avian Reproduction, Freshwater Fish Toxicity, Acute Toxicity to Freshwater Invertebrates, Acute Toxicity to Estuarine and Marine Organisms, Fish Early Life Stage and Aquatic Invertebrate Life Cycle, Aquatic Organism Accumulation Testing, and Simulated or Actual Field testing for Aquatic Organisms.

-Product Chemistry and Acute toxicity data are required.

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